

**Amendments to claims:**

This listing of claims will replace all prior versions and listings of claims in the application:

**Listing of Claims:**

1. (Currently amended)      An airway adapter comprising:
  - a first end section having an opening for connecting to an endotracheal tube adapter, said first end section also having formed therein a passage having an internal diameter;
  - a second end section for connecting to a ventilating tube connector, said second end section being in fluid communication with said first end section;
  - a breath sampling port intermediate said end sections, in fluid communication with said first end section; and
  - a tubular sliding insert which slides axially in said passage formed in said first end section, as said endotracheal tube adapter is pushed onto said airway adapter.
2. (Currently amended)      An airway adapter according to claim 1, wherein said insert has an internal bore of internal diameter which gradually increases towards an end of said insert near said sampling port, such that said internal diameter of said internal bore becomes essentially equal to said internal diameter of said passage.
3. (Previously presented)      An airway adapter according to claim 1, wherein said insert has a projection adapted to abut against a portion of said first end section, said projection providing an axial limit to motion of said insert into said passage.
4. (Previously presented)      An airway adapter according to claim 3, wherein said projection comprises an external lip on said insert.
5. (Currently amended)      An airway adapter according to claim 1, wherein said insert has an outer wall and said passage has an inner wall, at least one of said outer wall of said

insert and said inner wall of said passage having a surface profile such that friction between said insert and said passage prevents said insert from sliding freely within said passage.

6. (Currently amended) An airway adapter according to claim 1, wherein said endotracheal tube adapter has an inner bore, said inner bore and said internal bore of said insert at an end of said insert distant from said sampling port having essentially equal internal diameters, thereby providing a virtually smooth-walled transition from said inner bore of said endotracheal tube adapter to said internal bore of said insert.

7. (Currently amended) An airway adapter according to claim 6, wherein said endotracheal tube adapter also has an inner end wall, and said end of said insert distant from said sampling port abuts against said inner end wall thereby resulting in virtual isolation of void volume from said passage.

8. (Previously presented) An airway adapter according to claim 6, wherein said virtually smooth-walled passage is operative to allow a breath to pass essentially without affecting its waveform.

9. (Currently amended) An airway adapter according to claim 7, wherein said virtual isolation of void volume is operative to allow a breath to pass essentially without affecting its waveform.

10. (Currently amended) An airway adapter according to claim 7, wherein said virtual isolation of void volume from said passage is effective independently of the relative position in which said endotracheal tube adapter and said airway adapter are mated.

11. (Previously presented) An airway adapter according to claim 1, wherein said sampling port has openings located radially distant from the walls of said passage.

12. (Currently amended) An airway adapter comprising:  
a first end section having an opening for connecting to an endotracheal tube adapter, said first end section also having formed therein a passage having an internal diameter and an outer wall;

a second end section for connecting to a ventilating tube connector, said second end section being in fluid communication with said first end section;

a breath sampling port intermediate said end sections, in fluid communication with said first end section; and

a tubular sliding sleeve which slides axially on said outer wall of said passage formed in said first end section, as said endotracheal tube adapter is pushed onto said airway adapter.

13. (Original) An airway adapter according to claim 12 and also comprising a spring operative to push said sleeve axially in a direction away from said sampling port.

14. (Previously presented) An airway adapter according to claim 12, wherein the internal diameter of said passage increases towards an end of said passage near said sampling port.

15. (Currently amended) An airway adapter according to claim 12, wherein said endotracheal tube adapter has an inner bore, said inner bore and said passage at an end distant from said sampling port having essentially equal internal diameters, thereby providing a generally smooth-walled transition from said inner bore of said endotracheal tube adapter to said passage.

16. (Currently amended) An airway adapter according to claim 15, wherein said endotracheal tube adapter has an inner end wall, and an end of said sleeve distant from said sampling port abuts against said inner end wall, thereby resulting in virtual isolation of void volume from said passage.

17. (Previously presented) An airway adapter according to claim 15, wherein said virtually smooth-walled passage is operative to allow a breath to pass essentially without affecting its waveform.

18. (Currently amended) An airway adapter according to claim 16, wherein said virtual isolation of void volume is operative to allow a breath to pass essentially without affecting its waveform.

19. (Currently amended) An airway adapter according to claim 16, wherein said virtual isolation of void volume from said passage is effective independently of the relative position in which said endotracheal tube adapter and said airway adapter are mated.

20. (Previously presented) An airway adapter according to claim 12, wherein said sampling port has openings located radially distant from the walls of said passage.

21. (Previously presented) An airway adapter according to claim 12, wherein said end of said sleeve distant from said sampling port is constructed of a pliant material.

22. (Currently amended) An airway adapter according to claim 1, operative to nullify the effects of differing internal diameters and internal lengths of different endotracheal tube adapters.

23. (New) An airway adapter according to claim 12, operative to nullify the effects of differing internal diameters and internal lengths of different endotracheal tube adapters.

24. (New) An airway adapter according to claim 1, wherein said insert slides axially in said passage when said endotracheal tube adapter is pushed onto said airway adapter, to a position determined by said endotracheal tube adapter.

25. (New) An airway adapter according to claim 12, wherein said tubular sliding sleeve slides axially on said outer wall of said passage when said endotracheal tube adapter is pushed onto said airway adapter, to a position determined by said endotracheal tube adapter.

## Claim amendments

Claim 1 has been amended by the deletion of recitations of first, second and third internal diameters of the various bores, and by the addition of the limitation that the first end section **has an opening**. Support for this recitation is to be found in the specification in Figs. 2 to 5. In addition, the sampling port has been described as a **breath** sampling port. Support for this recitation is to be found in the specification on page 13, paragraph 5, line 3. Additionally, the tubular sliding insert is described as sliding axially in the passage formed in the first end section, **as the endotracheal tube adapter is pushed onto the airway adapter**. Support for this recitation is to be found in the specification on page 14, paragraph 2, lines 9-11.

Claim 5 has been amended by the additional recitation that the friction between the insert and the passage may be due to the surface profile on either or both of the inner wall of the passage and the outer wall of the insert. Support for this recitation is to be found in the specification on page 12, paragraph 4, lines 3-6.

Claim 6 has been amended by the addition of the recitation deleted from claim 1 that the **“endotracheal tube adapter has an inner bore”**. Additionally, the claim has been amended to recite “a smooth-walled **transition**”, support for which is to be found in the specification on page 17, paragraph 4, line 3.

Claim 7 has been amended by the replacement of the recitation “end of said inner bore of said endotracheal tube” by the simpler recitation **“inner end wall”** to add clarity to the claim recitation. Support for this amendment is to be found in the specification on page 14, paragraph 2, line 10, as amended in the present amendment. Furthermore, claims 7, 9 and 10 have been amended by the replacement of the recitation “elimination of void volume” with the recitation **“isolation of void volume”**, support for which is to be found in the specification on page 14, paragraph 3, lines 2-3.

Claim 12 has been amended in a manner equivalent to the amendments made to claim 1.

Claim 15 has been amended in a manner equivalent to the amendments made to claim 6, except that the recitation "transition" was already to be found in claim 15.

Claim 16 has been amended in a manner equivalent to the amendments made to claim 7.

Claims 18 and 19 have been amended in a manner equivalent to the amendments made to claims 7, 9 and 10.

Other amendments made to the claims are of a formal nature, involving rearranging of recitations to clarify correct antecedent bases for all of the claims.

#### **New claims**

New dependent claim 23 is the equivalent to claim 22, but dependent on claim 12 instead of on claim 1.

New dependent claim 24 recites that the insert slides in the passage of the adapter to a position determined by the endotracheal tube adapter, support for which is to be found in the specification on page 15, paragraph 2, lines 7-8, and the associated Figs. 3 and 4.

New dependent claim 25 is the equivalent to claim 24, but dependent on claim 12 instead of on claim 1.

#### **Claim rejections - 35 USC § 102**

The Examiner has repeated the rejections made in the previous Office Action dated October 16, 2003, whereby claims 1-7, 12-16 and 21 were rejected under 35 U.S.C 102(a) as being anticipated by Enzinger (DE 298 11 374 U1) The Examiner stated in that office action that "In regard to claims 1 and 12, Enzinger discloses an airway adapter (see fig) having a first end section (11) for connecting to an e-tube adapter having an inner bore, said first end section having a passage formed therein, a second end section (12) for connecting to a ventilating tube connector, said second end section being in fluid connection with said first end section, a sampling port (13) intermediate said end section in fluid communication with said first end section and a tubular insert (with regards to claim 1)

or a sleeve (with regards to claim 12) (5-9) with an internal bore (interior defined by 7 and 8) which slides axially in said passage.”

The applicants reiterate their previous submission that the Examiner’s interpretation of what is shown in Enzinger is incorrect. The applicants respectfully submit that:

(i) Contrary to what is asserted by the Examiner, the insert shown in the Enzinger patent does not and cannot “slide axially in said passage”, said passage having been defined by the Examiner as being in the first end section (11), this being the section at the left hand side of the device shown in the drawing in Enzinger. The insert shown in Enzinger is prevented from entering the passage in the first end section (11) by means of a raised edge at the third opening (3), as shown in the drawing in Enzinger. If that edge were not present and the Enzinger insert were allowed to slide into the passage in the first end section, the patient’s breathing path between the first and second openings would be blocked by the insert, thereby suffocating the patient! In U.S. Patent No. 6,516,803, which corresponds to the German Patent DE 298 11 374 U1 cited by the Examiner, the insert is described in col. 3, lines 38-39, as a “piston .... displaced in the direction of the fourth opening”. This fourth opening is described in col. 3, lines 28-30 of U.S. Patent No. 6,516,803 as being “on the side **opposite** the first opening” (emphasis added), and therefore cannot be described as sliding axially in a passage in the first end section.

In contrast to what is shown in the Enzinger patent, amended claim 1 of the present application now recites:

“a first end section **having an opening** for connecting to an endotracheal tube adapter, **said first end section having formed therein a passage** ..... ;  
.....and

a tubular sliding insert **which slides axially in said passage formed in said first end section**, as said endotracheal tube adapter is pushed onto said airway adapter” (emphasis added).

Furthermore, even if the Examiner were to consider the right hand end as being the first end section of the Enzinger device, this being the end having the sliding insert, the applicants respectfully submit that the current recitation in amended claim 1, that the airway adapter comprises “a first end section **having an opening** for connecting to an endotracheal tube adaptor”, still distinguishes the presently claimed invention from the Enzinger device, which has a **closed** end section (emphases added).

(ii) The opening 3 in the Enzinger patent, described by the Examiner as “a sampling port (13) intermediate said end section” is described in U.S. Patent No. 6,516,803 itself as “an opening for draining sputum”. According to the diameter of this opening in the drawing, it is indeed suitable for such, but not for breath sampling. A breath sampling port, as is known to one skilled in the art, must have a diameter significantly smaller than that of the airways, in order to accurately sample the breath in the airways without disturbing the respiration of the patient. The diameter of the sputum extraction port 3 shown in the Enzinger patent is far too large to serve as a breath sampling port. The applicants respectfully wish to justify use of the comparative dimensions of the openings shown in the Enzinger patent, since in the instant office action, the Examiner himself has used such dimensions to assert that the Enzinger patent anticipates previously filed claims of the present application, which recited various internal diameters.

In contrast to what is shown in the Enzinger patent, amended claim 1 of the present application now also recites:

“a **breath** sampling port intermediate said end sections.....” (emphasis added), which the applicants assert is nowhere shown or suggested in Enzinger.

(iii) What the Examiner describes as the “insert” of the Enzinger patent, is in fact a piston, which is described in U.S. Patent No. 6,516,803 in col. 3, lines 38-39, as being “displaced in the direction of the fourth opening **by the pressure of the exhaled air.**”

In contrast to what is shown in the Enzinger patent, in which the “insert” undergoes motion under the pressure of the exhaled air, and in which the motion is unrelated to the action of attachment of the endotracheal tube adapter to the airway adapter, amended claim 1 of the present application now recites:

“ .....a tubular sliding insert which slides axially in said passage formed in said first end section, **as said endotracheal tube adapter is pushed onto said airway adapter**” (emphasis added).

Similar arguments to those presented above with respect to the insert of claim 1, can also be brought with respect to the sleeve recited in claim 12.



The applicants therefore respectfully submit that, for all of the above-stated arguments, neither amended claim 1 nor amended claim 12 are anticipated by the Enzinger prior art, and are deemed allowable.

### **Claim rejections - 35 USC § 103**

The Examiner has repeated the rejections made in the previous Office Action dated October 16, 2003, whereby claims 8-11, 17-20 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Enzinger, for the various reasons elucidated in the Office Action. Since claims 8-11 and 22, amended where relevant, are dependent on amended claim 1, and add additional patentable matter, and amended claim 1 is deemed allowable, the applicants submit that claims 8-11, amended where relevant, are also deemed allowable. Since claims 17-20, amended where relevant, are dependent on amended claim 12, and add additional patentable matter, and amended claim 12 is deemed allowable, the applicants submit that claims 17-20, amended where relevant, are also deemed allowable.

In the instant Office Action, dated May 4, 2004, in response to the arguments presented by the applicants in their amendment filed on February 10, 2004, the Examiner has commented that:

"Contrary to applicants assertions t(h)e reference to Enzinger does disclose(s) axial sliding motion of the insert element 8 w(h)ere said sliding element does have a diameter that is different from the main passageway diameter. It should be noted (that) that the first end section comprises two openings 11 and 12 which have different diameters. In a reasonably broad reading of the claims, this would meet the claimed dimensions of the first and second passageway diameters."

The instant office action includes two contradictory statements regarding the Examiners' interpretations of the Enzinger patent. In the now-repeated rejections of the office action dated October 16, 2003, the Examiner attributes the "first end section" of Enzinger to opening 11, while the "second end section" is attributed to opening 12. On the other hand, in the present office action, in his rejection of the applicants' arguments, the Examiner states that "the first end section comprises two openings 11 and 12". For this

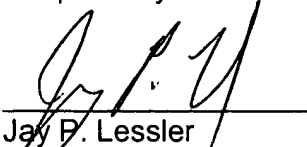
reason, the applicants have not been able to comment on the Examiner's rejections of their arguments. However, the applicants do respectfully submit that, the Examiner has related in the previously amended claims, only to recitations regarding the various supposedly different diameters of the openings and bores of the presently claimed invention, and has not related to any of the substantive arguments presented in the amendment. Furthermore, the applicants submit that the claim amendments reciting various differently named diameters were made in order to distinguish between various openings and bores of the present claimed invention for the purpose of providing correctly referred antecedent basis throughout the claims. Nowhere did the applicants make any reference to any actual difference in the size of the various differently named diameters. The applicants have deleted all references to differently named diameters in the currently amended claims, such that this aspect of the Examiner's response to the applicants' arguments is rendered moot.

## **Conclusion**

The applicants therefore respectfully submit that, in the light of all of the arguments mentioned above, all of the amended, previously presented and originally filed claims 1-22, and new claims 23-25 are novel and unobvious over the prior art cited by the Examiner, that they recite patentable material, and are therefore all deemed to be allowable. Entry of this amendment, and reconsideration and prompt allowance of this application are therefore respectfully requested.

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Respectfully submitted,

  
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